

amount varying over time from \$.10 to \$.50 per claim. (Paul Ex. 1 (Gorospe Decl.), at ¶¶ 5a, 5b, 6.)

4. The Cost of the Drug Product was set at *the lowest of* the drug's Estimated Acquisition Cost ("EAC"), the Federal Allowable Cost (FAC, a/k/a FUL), or (c) the Maximum Allowable Ingredient Cost (MAIC).¹ (Paul Ex. 1 (Gorospe Decl.), at ¶ 5a, 5b.)

5. The Estimated Acquisition Cost for the Subject Drugs was determined at all relevant times at the AWP's reported by First Data Bank ("FDB") less a discount of either 5% (from 1994 through October 2002), 10% (from November 2002 through August 2004), or 17% (August 2004 through December 2004). (Paul Ex. 1 (Gorospe Decl.), at ¶¶ 5b, 7.)

B. Sandoz Set and Reported AWP's for Its Products Without Regard to The Actual Prices Being Generally and Currently Paid By Providers.

6. Throughout the relevant time period, Sandoz set AWP's for its products and reported those prices to pricing compendia, including FDB. (Paul Ex. 2 (3/26/08 Christopher Worrell Dep.), at 349:11-20.)

7. At the time Sandoz launched a new product, there was no predictable relationship between the AWP Sandoz set for that product and the price at which Sandoz actually sold that product. (Paul Ex. 3 (6/11/07 Kevin Galownia Dep.), at 169:5-17.)

8. When it was the first company to market and sell a particular generic product, Sandoz generally set and reported as an AWP for that particular product a price 10 to 20 percent below the AWP for the corresponding brand product, regardless of the price at which Sandoz actually sold that product. (Paul Ex. 3 (6/11/07 Kevin Galownia Dep.), at 162:14-20, 169:5-9; Paul Ex. 4 (1/25/07 Armando Kellum Dep.), at 79:1-14.)

¹ There are no claims paid at MAIC at issue in this case.

9. When Sandoz launched a product and there was already a competitive generic product on the market, Sandoz set its AWP by reference to the competitor's AWP. (Paul Ex. 5 (6/19/08 Kevin Galownia Dep.), at 70:19-71:11.)

10. Sandoz knew that the generic market was very competitive (Paul Ex. 2 (3/26/08 Christopher Worrell Dep.), at 469:22-470:2) and that market prices for generic drugs tended to decline significantly after additional participants entered the market. (Paul Ex. 4 (1/25/07 Armando Kellum Dep.), at 87:20-88:7.)

11. Sandoz generally did not change its reported AWP's in response to changes in transaction prices for its complaint products. Its practice was to set a product's AWP at launch and not change that AWP. (Paul Ex. 3 (6/11/07 Kevin Galownia Dep.), at 183:9-14; (Paul Ex. 2 (3/26/08 Christopher Worrell Dep.), at 467:21-468:7.)

12. On occasion, Sandoz raised the AWP for a product. (Paul Ex. 5 (6/19/08 Kevin Galownia Dep.), at 57:20-58:1.) Since Sandoz did not actually sell its products at AWP, (Paul Ex. 2 (3/26/08 Christopher Worrell Dep.), at 510:5-8), the only reason for raising its AWP was to increase the reimbursement spread. (Paul Ex. 5 (6/19/08 Kevin Galownia Dep.), at 58:2-16.)

13. Sandoz was aware that it was necessary to report AWP's to the pricing compendia in order for its products to be reimbursed by third party payers, such as Medi-Cal. (Paul Ex. 4 (1/25/07 Armando Kellum Dep.), at 46:18-47:11; Paul Ex. 5 (6/19/08 Kevin Galownia Dep.), at 72:8-21.)

14. FDB published the suggested AWP's reported by Sandoz as the AWP's for Sandoz's products. (Paul Ex. 2 (3/26/08 Christopher Worrell Dep.), at 358:13-359:1.)

C. Sandoz Was Aware of the Prices Providers Paid For Its Products.

15. Sandoz maintained databases through which it regularly tracked the prices at which its products were being sold. (Paul Ex. 6 (1/27/09 Frank Stiefel Dep.), at 378:17-379:18.)

16. For internal business purposes, Sandoz calculated the average sales prices for its products on a regular basis. (Paul Ex. 2 (3/26/08 Christopher Worrell Dep.), at 486:23-487:10, Ex. 42.)

17. Sandoz contracted directly with large retail pharmacy chains (Paul Ex. 7 (11/13/08 Frank Stiefel Dep.), at 107:25-108:25) and group purchasing organizations (Paul Ex. 8 (5/2/08 Wanda Edwards Dep.) at 26:1-5) for the sale of its products.

18. Sandoz did not report its transactional prices, nor any average or compilation of these prices, to the pricing compendia or to Medi-Cal as its products' AWP or otherwise. (Paul Ex. 6 (1/27/09 Frank Stiefel Dep.), at 379:19-380:7.)

19. There was no fixed or predictable relationship between the AWP that Sandoz reported to FDB and the prices at which its products were sold to the retail class of trade. (Paul Ex. 3 (6/11/07 Kevin Galownia Dep.), at 169:5-17.)

D. Sandoz's Knowledge of Medicaid and Medi-Cal Policies

20. Sandoz was aware of or on notice of Medicaid and Medi-Cal reimbursement policies in general. (Paul Ex. 7 (11/13/08 Frank Stiefel Dep.), at 70:14-25; Paul Ex. 9 (5/6/09 Ronald Hartmann Dep.), at 330:21-332:14.)

21. Sandoz was aware of or on notice that Medi-Cal reimbursed providers for pharmaceutical products based on the reported AWP of the products. (Paul Ex. 9 (5/6/09 Ronald Hartmann Dep.), at 330:21-332:14.)

E. Claims Submitted For All of Sandoz's Subject Drugs Were Materially False.

22. Plaintiffs' expert, Dr. Leitzinger, used data provided by Sandoz to estimate the average prices paid by pharmaceutical wholesaler's customers [i.e., providers] for each of the 149 relevant Sandoz NDCs. Dr. Leitzinger did that by calculating the prices that wholesalers paid to Sandoz for each NDC and then applying a wholesaler markup to those prices to estimate the total amount that customers paid to wholesalers for each such NDC. (Paul Ex. 10 (Leitzinger Decl.), at ¶ 4). His methodology is explained more fully at paragraphs 12-20 of his Report, which is attached as Ex. A to his Declaration. The wholesaler markup that Dr. Leitzinger used was based on data contained in the "Industry Profile and Healthcare Factbook," published by the Healthcare Distribution Management Association. That markup ranged over time between 3.7 percent and 5.4 percent. (Paul Ex. 10 (Leitzinger Decl.), Ex. A at ¶ 20, n.20.)

23. Ex. 4 to Dr. Leitzinger's Report shows in column (6) the "spread" (the difference between the average net quarterly prices that he calculated and the reported AWP) for each of the 149 relevant Sandoz NDCs on a quarter-by-quarter basis from the first quarter of 1994 through the fourth quarter of 2004. (Paul Ex. 10 (Leitzinger Decl.), at ¶ 5.)

24. For over 95 percent of the Sandoz NDC/quarter combinations for which he had complete data, the AWP reported by Sandoz exceeded the average net quarterly prices paid by wholesalers' customers by at least 100 percent. For 82 percent of those NDC/quarter combinations, the spread exceeded 300 percent, with some greater than 2,000 percent. (Paul Ex. 10 (Leitzinger Decl.), at ¶ 6.)

25. For purposes of calculating the overpayments made by the State for the 149 relevant Sandoz NDCs, Dr. Leitzinger excluded claims for which the actual reimbursement did not exceed the average net price paid by wholesalers to Sandoz by at least 25 percent. For each remaining claim, he calculated the difference between the actual ingredient cost reimbursed by

the State and an amount 25 percent above the average net price paid by wholesalers to Sandoz. That difference was the overpayment he found. (Paul Ex. 10 (Leitzinger Decl.), at ¶ 7.)

F. Sandoz Acted Knowingly in Making the Above False Statements.

26. Sandoz did not define AWP as a price paid by retailers to wholesalers for its products. Instead, AWP was a price set by Sandoz only to ensure a generic designation from the pricing entities, such as FDB. (Paul Ex. 2 (3/26/08 Christopher Worrell Dep.), at 383:21-384:9.)

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on November 24, 2009, a copy to Lexis-Nexis for posting and notification to all parties.

/s/ Nicholas N. Paul
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